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10/548,403

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Marie Bendix Hansen

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FOLEY AND LARDNER LLP

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

KIM, ALEXANDER D

ART UNIT

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09/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/548,403	Applicant(s) HANSEN ET AL.	
	Examiner ALEXANDER D. KIM	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office actions, an Advisory Action after Final rejection (mailed on 06/22/2010), Applicants filed a Notice of Appeal received on 09/13/2010 with claim amendment.

Upon reconsideration by the Examiner, new rejections have been made as noted hereafter and prosecution has been reopened. In said amendment, claims 8 and 14 are cancelled; claims 1 and 9 are amended.

Claims 1-7, 9-13 and 15-17 are pending and will be examined in the instant office action.

Claim Interpretation

2. Claim 1 (Claims 2-7, 9-13 and 15-17 dependent therefrom) recites the limitation "a linear flow rate of at least 1,500 cm/hour" is broad to encompass a variety of flow rate depending on a column size (a cross sectional area of column, for example). In view of instant dependent claims 15 and 17 (which must be further limiting from their independent claim 1), the flow rate of claim 1 is broader to encompasses the flow rate of claims 15 and 17 (i.e., 50l/hour or 100 l/hour, respectively). Therefore, any flow rate represented by cm/hour or cm/min are obvious and/or anticipates each other unless column diameter is limited to a specific size in any patent application, US patent and/or reference(s) including instant application. The diameter of column is recited in instant

claim 4; however, the term "about" makes the claim to encompass broadly, that is smaller than 50 cm as well as larger than 200 cm, for example.

Priority

3. It is noted that instant limitation of "at least 40°" is not supported by the foreign priority (i.e., Denmark PA 2003 00443 filed on 3/21/2003). Thus, instant claims 1-7, 9-13 and 15-17 have priority date of 3/19/2004 which is filing date of PCT/DK04/00187.

Withdrawn-Claim Objections

4. The previous objection of Claim 1 for not reciting a conjunction following step d) of claim 1 is withdrawn by virtue of applicants' amendment filed on 6/11/2010.

5. The previous objection of Claim 1 for reciting the phrase "expanded bed adsorption column", "expanded bed column", "chromatographic column" (claim 1, part c)), and "column" (claim 1, part d)), which terms all refer to the same column, is withdrawn by virtue of applicants' amendment filed on 6/11/2010.

New-Claim Objections

6. Claims 1-7, 9-13 and 15-17 are objected to because of the following informalities:

Claim 1 (Claims 2-7, 9-13 and 15-17 dependent therefrom) recites "process water from the food and/or feed industry". It should be ---processed water ...---, or ---water from the food and/or feed industry---, to improve the format of claim 1.

Appropriate correction is required.

New-Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7, 9-13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lihme et al. (WO 02/096215, published May 12, 2002; as cited in PTO 892 mailed on 9/23/2009).

Lihme et al. teach a general method for the fractionation of a protein-containing mixture wherein the protein- containing mixture is selected from the group consisting of milk, milk derived products, milk derived raw materials, vegetable derived products, vegetable derived extracts, fruit derived products, fruit derived extracts, fish derived products, and fish derived extracts, said method comprising the steps of: a) optionally adjusting the pH of the mixture; b) applying said mixture to an adsorption column comprising an adsorbent, said adsorbent comprises a particle with at least one high density non-porous core, surrounded by a porous material, the adsorbent having a

particle density of at least 1.5 g/ml and a mean particle size of at most 150 μ m; c) optionally washing the column ; d) eluting at least one protein from the adsorbent (see claim 1 or claim 25); wherein said method encompasses a flow-rate of about 5-50 cm/min (i.e., 300 to 3000 cm/hour; see claim 3); wherein said method encompasses species of method for purifying lactoferrin (LF) and lactoperoxidase (LP) protein from sweet whey having temperature of 50° C (see Example 11 on pages 36-37) in Expanded Bed Adsorption column (known as EBA). Thus, Lihme et al. teach a protein isolating method which meets the all limitations in instant **claims 1, 6, 7, 9, 13**. The purified LP and/or LF is shown in SDS-PAGE gel in figure 5 which shows Molecular weight is larger than 2 kDa (see Fig. 6 for relative size of protein compared to the standard); meeting the limitation of instant **claim 5**. Lihme et al. also teach a method of running an EBA column with diameter of 1.5 metre containing 265 litres of adsorbent can extract immunoglobulin from the whey with 690,000 litres per day (i.e., 28750 L/hour passing through at any given amount of adsorbent in column, 1 L of adsorbent, for example; see top of page 45 in Example 11); in view of broad terminology "about", meeting the limitations of instant claims **2-4, 15 and 17**. Lihme et al. also teach that EBA adsorbent has mean particle size of 56 micron having density of 2.4 g/ml, for example, (see middle of page 47); meeting the limitation of instant claims **10-12 and 16**.

8. Claims 1, 3-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Flickinger et al. (US Patent 5,837,826; issued Nov. 17, 1998) as evidenced by Protein Marker Broad Range (last viewed on 9/22/2010).

Flickinger et al. teach a method of isolating BSA (66 kDa, see bottom of 1st page, Protein Marker Broad Range) by loading sample containing BSA sample to an expanded bed adsorption chromatography (EBAC) packed with xirconium oxide adsorbent and eluting said BSA including "elevating the loading temperature from 25°C to 45° C" (see top of column 28); results shown in Figure 11; and also teach the EBAC purification method can have "linear fluid velocities at least about ... as high as 4000 cm/hour, can be obtained" (see column 8, line 57); meeting the limitation of instant claims **1, 5, 6, 9 and 13**. Flickinger et al. teach the mean particle size is within a range of about 30-400 μm (see second paragraph of column 7); meeting the limitations of instant claims **10-11 and 16**. Flickinger et al. teach the density of absorbent is about 2.5-3.5 g/cm^3 (1ml of liquid has a volume of 1 cm^3), see column 7, line 35; meeting the limitation of instant claim **12**. Flickinger et al. teach the column size of 2.5 x 15 cm for the expanded bed column thus, containing a certain amount of absorbent (see column 19, line 13); in view of broad and reasonable interpretation of the term "about", meets the limitations of instant claims **3-4**. Flickinger et al. teach the flow rate of

The BSA is immunogenic to certain animal and globular shape in nature; thus, the method of Flickinger et al. meets the limitation of instant claim **7**.

Withdrawn-Claim Rejections - 35 USC § 103

9. The previous rejection of Claims 1-2, 5-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lihme et al. (WO 02/096215, published May 12, 2002) as evidenced by Molecular Weight of IgG (last viewed Sep. 11 2009) is

withdrawn by further consideration by the Examiner and in view of new rejection above under 35 U.S.C. 102(b).

10. The previous rejection of Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lihme et al. (WO 02/096215, published May 12, 2002) as evidenced by Molecular Weight of IgG (last viewed Sep. 11 2009) as applied to claims 1-2, 5-15 above, and **further in view of** Olander et al., (Scandinavian Dairy Information, 2001, no. 2., pp. 22–25) is withdrawn by further consideration by the Examiner and in view of new rejection above under 35 U.S.C. 102(b).

New-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable Flickinger et al. (US Patent 5,837,826; issued Nov. 17, 1998) as evidenced by Protein Marker Broad Range (last viewed on 9/22/2010) in view of Lihme et al. (WO 02/096215, published May 12, 2002; as cited in PTO 892 mailed on 9/23/2009) and/or Olander et al., (Scandinavian Dairy Information, 2001, no. 2., pp. 22–25; as cited in PTO 892 mailed on 9/23/2009).

The teachings of Flickinger et al. as evidenced by Protein Marker Broad Range is described as set forth above.

Flickinger et al. do not teach a large EBA column having at least 50 L/hour applied per litre of adsorbent (which encompasses a column having more than 1 L of adsorbent).

Lihme et al. (WO 02/096215, published May 12, 2002; as cited in PTO 892 mailed on 9/23/2009) and/or Olander et al., et al. teach a method of running an EBA column with diameter of 1.5 metre containing 265 litres of adsorbent can extract immunoglobulin from the whey with 690,000 litre per day (i.e., 28750 L/hour passing through at any given amount of adsorbent in column, 1 L of adsorbent, for example; (see top of page 45 in Example 11 in Lihme et al.; or see bottom left column of Olander et al. on page 25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to purify a protein using a large EBA column with a reasonable expectation of success since scaling up of working chromatography can be performed by making a bigger column. The motivation to do so is provided by Lihme et al. who teach the usefulness of a large EBA chromatography in a food industry which requires to handle a large volume; for example, "This is in great part due to the large scale of the process required for milk and whey fractionation, typically involving extremely high volumes of raw material to be treated per day (e. g. several m³/hour) which requires extremely high efficiency and productivity of the EBA system" (see page 3, lines 24-30 in Lihme et al); or Olander et al. who teach a large industrial-scale EBA

method is now ready and cost-effective (see top left column, page 22). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

As noted above, Claim 1 (Claims 2-7, 9-13 and 15-17 dependent therefrom) recites the limitation “a linear flow rate of at least 1,500 cm/hour” is broad to encompass a variety of flow rate depending on a column size (a cross sectional area of column, for example). In view of instant dependent claims 15 and 17 (which must be further limiting from their independent claim 1), the flow rate of claim 1 is broader to encompasses the

flow rate of claims 15 and 17 (i.e., 50l/hour or 100 l/hour, respectively). Therefore, any flow rate represented by cm/hour or cm/min are obvious and/or anticipates each other unless column diameter is limited to a specific size in any patent application, US patent and/or reference(s) including instant application. The diameter of column is recited in instant claim 4; however, the term "about" makes the claim to encompasses broadly, that is smaller than 50 cm as well as larger than 200 cm, for example.

11. Claims 1-7, 9-13 and 15-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over allowed claims 1, 3-5, 7-16, 19-23 and 27-33 of U.S. Patent application 10/478,111 (U.S. Patent No. to be issued) in view of Lihme et al. (WO 02/096215, published May 12, 2002; as cited in PTO 892 mailed on 9/23/2009) and/or Olander et al., (Scandinavian Dairy Information, 2001, no. 2., pp. 22-25; as cited in PTO 892 mailed on 9/23/2009).

Claims 1, 3-5, 7-16, 19-23 and 27-33 of U.S. Patent application 10/478,111 encompasses a method for the fractionation of a protein by applying a protein containing mixture from a milk, milk derived products...fish derived extract as recited in claim 1 and eluting a protein from the adsorbent of expanded bed adsorption (EBA) column (see claims 10 and 23, of U.S. Patent application 10/478,111, for example) with "a flow-rate of at least 5cm/min" (i.e., at least 300 cm/hour). Claim of 21 is drawn to said purification method wherein at least one isolated protein mixture comprises at least 70% w/w purity which is represented by obvious species of a method step which comprises running an EBA column as disclosed in Example 11 fractionating LP protein

to 70% purity from the whey protein sample having temperature of 50° C (see Table on top of page 37), wherein mean particle size is 40 to 150 µm. All the other limitations which anticipates or obvious is disclosed in the specification of U.S. Patent application 10/478,111 or obvious for one skill in the art. According to MPEP 2144.05.II, “[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical”. For example, Lihme et al. (WO 02/096215) and Olander et al. teach an industrial scale EBA column having 265 liters of adsorbent and having a diameter of 1.5 meter (i.e., 1500 cm), see bottom of left column, page 25; and teach using EBA column with 690000 litre per 24 hours (i.e., 28750 l/hour; see left column, bottom, page 25); as well as all the limitations recited in instant claims as noted above. Thus, instant claims 1-7, 9-13 and 15-17 are obvious over allowed claims 1, 3-5, 7-16, 19-23 and 27-33 of U.S. Patent application 10/478,111.

12. Claims 1-7, 9-13 and 15-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23, 26-28 of U.S. Patent No. 7,368,141; claims 18-31 of U.S. Patent No. 6,783,962; claims 1-15 of U.S. Patent No. 6,498,236; or claims 1-6 of U.S. Patent No. 6,620,326 in view of Lihme et al. (WO 02/096215, published May 12, 2002; as cited in PTO 892 mailed on 9/23/2009) and/or Olander et al., (Scandinavian Dairy Information, 2001, no. 2., pp. 22–25; as cited in PTO 892 mailed on 9/23/2009).

As similarly noted in above nonstatutory obviousness-type double patenting rejection, claims in US patents above are drawn to a method of isolating protein(s) using expanded bed adsorption chromatography which anticipates and/or obvious in view of teachings of Lihme et al. (WO 02/096215, published May 12, 2002; as cited in PTO 892 mailed on 9/23/2009) and/or Olander et al. for all the same reasons stated above.

Additional References

Knut O. Strætkvern, Jurgen G. Schwarz, Dennis P. Wiesenborn, Elias Zafirakos and Allan Lihme, Expanded bed adsorption for recovery of patatin from crude potato juice, Bioseparation, 1999, Volume 7, Number 6, 333-345.

Lihme et al., Expanded Bed Adsorption., Downstream Processing of Proteins., Methods in Biotechnology, 2000, vol. 9, pages 121-139.

Extended reports from the 4th International Conference on Expanded Bed Adsorption, Florida, USA Sep 8-11, 2002, pages 1-68.

Pharmacia Handbook (1997). Introduction to Expanded Bed Adsorption, pages 1-160.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/
Examiner, Art Unit 1656